

April 25, 1999

1237 '99 APR 27 P1:42

Dockets Management Branch
(FDA-305), Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Subject: **DOCKET** No **99N-0386**

QUESTIONS: 1-5

PROPOSED ACTION:

**STAKEHOLDERS MUST DEMAND THAT CONGRESS REVERSE THE DRUG APPROVAL STAMPEDE CAUSED BY
"FAST TRACK" LEGISLATION**

ACCOUNTABILITY?

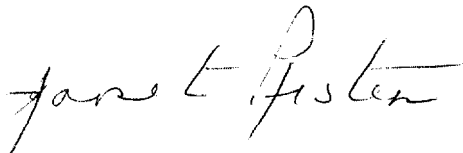
"Where billions of dollars of profits are at stake, the drug companies
simply cannot be their own policeman."
Excerpt: Los Angeles *Times*, June 28, 1998, **Column** Left/Robert Kuttner

THE RETURN OF THE FDA TO **ITS** STATUS AS **THE** INDEPENDENT, PREMIER CONSUMER **SAFETY** AGENCY,

INTEGRITY?

"Traditionally, the process of conducting clinical trials for new drugs
has been dominated by research universities, teaching hospitals and
government scientists not on drug company payrolls. In recent years,
more and more clinical investigations are being done by researchers
on contract to drug companies and for-profit companies are displac-
ing universities. There have been cases where a university-based re-
view panel set high standards and a drug company simply found a
more docile private contractor."
Excerpt: Los Angeles *Times*, June 28, 1998, Column Left/Robert Kuttner

THE WORDS INTEGRITY AND ACCOUNTABILITY MUST HAVE **FOUNDATION IN DEED**; NOT JUST A "SALES PITCH".



Janet Pfister
3652 E 17th Street
Long Beach, CA 90804-2001

99N-0386

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